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IS 12375 (Part 2) : 1993
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भाग 2 धात्विक और प्लास्टिक सामग्रियों से बने बियरिंग सतह

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 2 BEARING SURFACES MADE OF METALLIC AND PLASTIC MATERIALS

UDC 615·465 : 616·72

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NEW DELHI 110002

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Orthopaedic Instruments and Accessories Sectional Committee, MHD 2

NATIONAL FOREWORD

This Indian Standard, which is identical with ISO 7206-2 : 1987 'Implants for surgery — Partial and total hip joint prostheses — Part 2 : Bearing surfaces made of metallic and plastics materials' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use point (.) as the decimal marker.

In this adopted, standard reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 468 : 1982	IS 3073 : 1967 Assessment of surface roughness	Technically equivalent
ISO 7206-1 : 1985	IS 12375 (Part 1) : 1987 Partial and total hip joint prostheses: Part 1 Classification, designation of dimensions and requirements	Identical

The concerned technical committee has reviewed the provisions of ISO 4291 : 1985 referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard.

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 2 BEARING SURFACES MADE OF METALLIC AND PLASTIC MATERIALS

0 Introduction

This International Standard covering partial and total hip joint prostheses comprises the following four parts :

Part 1 : Classification, designation of dimensions and requirements.

Part 2 : Bearing surfaces made of metallic and plastics materials (this part of ISO 7206).

Part 3 : Determination of endurance properties of stemmed femoral components without application of torsion.

Part 4 : Determination of endurance properties of stemmed femoral components with application of torsion.

1 Scope and field of application

This part of ISO 7206 specifies requirements for the bearing surfaces of those types of total and partial hip joint prostheses that provide a joint replacement of ball and socket configuration, as follows :

a) roundness and surface finish requirements and dimensional tolerances for metal femoral components of total hip joint prostheses that are in accordance with classification c) of ISO 7206-1;

b) surface finish requirements and dimensional tolerances for plastics acetabular components that are in accordance with classification b) of ISO 7206-1;

c) roundness and surface finish requirements for metal femoral prostheses for partial hip joint replacement that are in accordance with classification a) of ISO 7206-1.

2 References

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

ISO 4291, *Methods for the assessment of departure from roundness — Measurement of variations in radius.*

ISO 7206-1, *Implants for surgery — Partial and total hip joint prostheses — Part 1 : Classification, designation of dimensions and requirements.*

3 Requirements

3.1 Total hip joint prostheses

3.1.1 Femoral component [in accordance with classification c) of ISO 7206-1]

3.1.1.1 Roundness

When measured in accordance with the minimum zone centre (MZC) method given in ISO 4291, the departure from roundness in more than one plane of the spherical bearing surface of a femoral component made of stainless steel or cobalt-based alloy shall have a radial separation value not greater than 5 µm, and that of a femoral component made of titanium alloy shall have a value not greater than 8 µm.

3.1.1.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of a femoral component made of stainless steel or cobalt-based alloy shall have an R_a value not greater than 0,05 µm, and that of a femoral component made of titanium alloy shall have an R_a value not greater than 0,1 µm.

NOTE — The following details should be reported :

a) stylus tip radius;

b) cut-off length of measuring instrument;

c) position of measurement on specimen.

When inspected visually under X2 magnification, the head of the component shall be free from embedded particles, defects with raised edges, and from scratches and score marks.

3.1.1.3 Dimensional tolerances

The spherical bearing surface shall have a diameter equal to the nominal diameter within a tolerance of $^{0}_{-0,2}$ mm.

3.1.2 Plastics acetabular component [in accordance with classification b) of ISO 7206-1]

3.1.2.1 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of the acetabular component shall have an R_a value not greater than 2 µm.

NOTE — The following details should be reported :

a) stylus tip radius;

b) cut-off length of measuring instrument;

c) position of measurement on specimen.

When inspected with normal or corrected vision, the bearing surface shall be free from scale, embedded particles and from scratches and score marks other than those arising from the finishing process.

3.1.2.2 Dimensional tolerances

The spherical socket shall have a diameter equal to the nominal diameter within a tolerance of $^{+0,1}_{+0,3}$ mm at a temperature of 20 ± 2 °C (i.e. it shall be oversized within the given tolerance).

3.2 Metal femoral prostheses for partial joint replacement [in accordance with classification a) of ISO 7206-1]

3.2.1 Roundness

When measured in accordance with the MZC method given in ISO 4291, the departure from roundness in more than one plane of the spherical bearing surface of femoral prostheses made of stainless steel, cobalt-based alloy or titanium alloy shall have a radial separation value not greater than 70 µm.

3.2.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of femoral components made of stainless steel, cobalt-based alloy or titanium alloy shall have an R_a value not greater than 0,5 µm.

NOTE — The following details should be reported :

a) stylus tip radius;

b) cut-off length of measuring instrument;

c) position of measurement on specimen.

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